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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 864,873	05 25 2001	John F. Rossi	1954-330	2281

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12 31 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/864,873

Applicant(s)

ROSSI ET AL.

Examiner

Karen A. Lacourciere

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the methods of claim 11-14 use the RNA molecule of Group I and, therefore, does not present an undue burden on the examiner. This has not been found to be persuasive because RNA molecule of Group I can be used in a materially different method than the method of treatment for HIV of claims 11-14. For example, the RNA molecule Group I can be used in vitro, in a method of delivery of RNA to a nucleus, which is materially different than the method of inhibiting HIV replication of claims 11-14.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

***Priority***

Support for the subject matter of an RNA comprising a TAR element and an RNA or portion of an RNA targeting nucleoli could not be found in the provisional application 60/206,976 and, therefore, priority for this subject matter is only given back to the filing date of the instant application, May 25, 2001. Applicant is invited to point out specific support for this subject matter in 60/206,976 to receive benefit of the earlier filing date.

***Specification***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see for example page 12 and 14). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites an "HIV TAR element". It is unclear what is encompassed in the term "HIV TAR element", for example, does this term mean any "element" of an HIV TAR sequence, i.e. any portion of the sequence, or does the term indicate the entire sequence of an HIV TAR sequence, or any sequence which has TAR activity or any sequence encoding an HIV TAR sequence? Claims 2-6 and 8-10 are indefinite for the same reasons due to dependence on claim 1. Claim 7 is dependent upon claim 1, however, claim 7 is not rejected under these grounds because the TAR element has been defined by specific sequence.

Claim 1 is indefinite due to the recitation "targets nucleoli in cells". It is unclear what the term "targets" would encompass. For example, does the term "targets" require that an RNA be transported into nucleoli, that the RNA bind to a nucleoli, or that an RNA have another activity related to nucleoli, e.g. inhibiting an activity within the nucleoli? Claims 2-10 are indefinite for the same reasons due to dependence on claim 1.

Claim 1 is indefinite due to the recitation "portion of an RNA which targets nucleoli in cells". It is unclear what RNA molecules are encompassed in claim 1 because it is unclear whether the claim is directed to any portion of an RNA that targets nucleoli, for example, even a single nucleotide of an RNA which targets nucleoli, or is the claim directed to portions of RNA wherein the portion must retain the ability to target nucleoli. Claims 2-10 are indefinite for the same reasons due to dependence on claim 1.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Browning et al. (J. Virol. 73(6): 5191-5195, 1999, cited on PTO form 1449 filed August 2, 2001).

Browning et al. disclose a vector comprising an RNA molecule comprising an HIV TAR element, further comprising a portion of a snoRNA. The RNA molecule comprised within the vector disclosed by Browning et al. comprises a "portion" (e.g., at least one nucleotide) of a C/D box snoRNA, including a U16 snoRNA. The vector disclosed by Browning et al. comprises an RNA pol II promoter sequence and is comprised within a cell. Therefore, Browning et al. anticipates claims 1-5 and 8-10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
December 29, 2002

  
**KAREN LACOURCIERE**  
**PATENT EXAMINER**